

REMARKS

Status of Claims

Claims 1 and 84-136 were pending prior to entry of this paper.

Claims 130-136 have been withdrawn from consideration.

Claims 84, 86, 87, 89, 90, 107-117, and 121-129 are cancelled herein without prejudice or disclaimer of Applicants' right to pursue the canceled subject matter in one or more related applications.

Claims 85, 91, 93, 95, 97, 130, and 134-136 are amended herein. Claims 161-164 are newly added. No new matter is introduced by the amendments or newly added claims.

Claim Rejections

Claims 1, 84, 86, 87, 91-94, 107, 116 and 117 stand rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 5,804,203 to Hahn et al. ("Hahn"). Claims 108 and 109 are rejected under §102(b) as anticipated by Hahn or, in the alternative, as obvious over Hahn under §103. Claims 85, 88, 111, 121, 122 and 129 stand rejected as obvious over Hahn under §103 and claims 89 and 123-128 are rejected under §103 as obvious over Hahn in view of U.S. Patent Pub. 2002/0012982 ("Blakesley"). Claims 90, 110 and 112-115 are rejected as unpatentable under §103 over Hahn in view of U.S. Patent No. 5,700,476 ("Rosenthal"). Applicants traverse these rejections. The patentability of all claims over Hahn is addressed below.

Each of the independent claims of the present application, viz., claims 1, 91, 93, 95, 97, and 144, call for a "swab" which comprises gelatine or collagen. Hahn does not teach or remotely suggest such a swab. Hahn is directed to a strontium-containing formulation for reducing skin irritation. Hahn discloses an extensive list of "topical vehicles and vehicle components for use in the formulations" at column 17, lines 1-33, among which "protein-based materials such as collagen and gelatin" are mentioned. Aside from this passage, no other reference is made to collagen or gelatin. In the next paragraph in column 17, lines 44-54, "[t]ypical modes of delivery" are discussed, among which a "physical applicator" is referenced, including a "swab." The Examiner relies on these two disparate teachings to suggest that Hahn discloses "a swab applicator which is a natural or synthetic absorbent material comprising

collagen particles.” However, there is no teaching that the swab of Hahn comprises collagen or gelatine. Rather, to arrive at such a article from the disclosure of Hahn, one must (i) select “collagen” or “gelatin” from the extensive list of vehicles, and (ii) select a “swab” from the extensive list of delivery modes, and (iii) infuse the swab with collagen particles -- with no guidance or suggestion to do so. To anticipate, a reference must disclose the claimed invention “without *any* need for picking, choosing, and combining various disclosures not directly related to each other by the teachings of the cited reference.” In re Arkley, 455 F.2d 586 (CCPA 1972). Applicants submit that all pending claims are novel over Hahn and withdrawal of the anticipation rejections is warranted.

Moreover, there is no suggestion in Hahn that would have motivated one skilled in the art to prepare a gelatin or collagen-containing swab. While the use of cotton swabs to apply solutions to the skin is disclosed in Example 1 of Hahn [col., 22, line 46; col. 24, line 33-41], they are used to apply alcohol-based solutions -- not gelatine or collagen-based materials. Indeed, one skilled in the art would not typically have looked to swabs to deliver collagen or gelatine-based materials since these are not liquid materials. Applicants submit that the Examiner is engaging in a hindsight reconstruction of the invention by modifying Hahn in a manner not suggest by Hahn itself or by the art in general without articulating any motivation or apparent rationale for doing so. Additional reasons that the various independent claims are patentable by Hahn are discussed below.

With respect to independent claim 1, the Examiner contends that Hahn discloses “a device comprising i) a swab applicator which is a natural or synthetic absorbent material comprising collagen particles; and ii) a support in the form of a stick fixed to said swab by adhering the instant formulation comprising collagen to said stick.” In addition to arguing that Hahn discloses “a swab applicator which is a natural or synthetic absorbent material comprising collagen particles” (which it does not), the Examiner further contends that “a support in the form of a stick fixed to said swab by adhering the instant formulation comprising collagen to said stick” is disclosed. The Examiner improperly reads into the disclosure of a “swab” that it has a stick attached to it when in fact the disclosure clearly lists a “stick” as a delivery form distinct from a “swab.” There is clearly no teaching or suggestion in Hahn of a swab comprising collagen or gelatine, let alone one having a support attached thereto.

Independent claim 91 is directed to a “kit” comprising “a device for sampling or collecting comprising a swab comprising gelatine or collagen” and “an agent selected from the group consisting of a neutral diluent, an anti-microbial agent, a disinfecting agent, and a dispersion agent.” As discussed above, Hahn does not teach or remotely suggest a swab comprising gelatine or collagen and thus independent claim 91 cannot be anticipated for at least this reason. Moreover, there is no disclosure in Hahn of a kit comprising such a swab. The Examiner points to column 18, lines 61-62 of Hahn for the teaching of “a neutral diluent in the form of a water solvent,” but even assuming a swab comprising gelatine or collagen were disclosed in Hahn (which it is not), the use of water as a solvent for the disclosed topical formulations of strontium cation cannot fairly be said to comprise a “kit” of the swab and water. Moreover, the Examiner is again engaging in hindsight because there is nothing in Hahn that would have motivated the selection of water in combination with collagen or gelatin as the vehicle for the strontium formulation, and a swab as the mode of delivery. For these additional reasons, Applicants respectfully submit that independent claim 91 is patentable over Hahn.

Independent claim 93 and newly presented independent claim 144 are directed to methods “for collecting a target from a collection medium” comprising the steps of (i) providing a swab or a device comprising a swab comprising gelatine or collagen, (ii) making contact between the swab and the target, and (iii) and transferring the target from the swab to a first transfer medium by releasing said target from said swab into the first transfer medium. Independent claim 97 is directed to a “method of lowering the amount of a target in a sample area” but otherwise contains the same limitations of a “swab comprising gelatine or collagen” and “transferring the target from the swab to a first transfer medium.” Not only does Hahn not disclose a swab comprising collagen or gelatine, it is further deficient in not disclosing or suggesting the steps of contacting the swab with a target and transferring the target to a medium. Hahn is concerned only with topical application rather than obtaining a target sample from a surface and transferring the target to a medium. The Examiner states that “Hahn teaches a method for collecting a target (skin cells from skin area) from a collection medium (i.e. the swab in the form of the collagen sponge application) comprising making contact between the swab” and the target. Hahn does not remotely contain such teachings. The Examiner cites to column 22, lines 46-48 which describes using a cotton swab or sponge applicator to apply the alcohol-based strontium formulation to the face. However, the applicator of that Example does not

comprise collagen or gelatine. Moreover, there is no disclosure, express or otherwise, that skin cells were transferred to the applicator. The Examiner's contention that skin cells are collected is mere speculation as no evidence has been produced to demonstrate that the methodology of Hahn would necessarily transfer skin cells. "Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thin may result from a given set of circumstances is not sufficient." Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). For at least these reasons, Applicants submit that independent claims 93, 97 and 144 are patentable over Hahn.

Applicants note that the Examiner does not cite Hahn as a primary reference against independent claim 95 but rather rejects claims 95-106 and 118-120 as obvious under §103 over Blakesley in view of Hahn. Independent claim 95 recites a "method for sampling an area for a target" which comprises the step of "swiping the surface of the area with a pre-wetted swab comprising a gelatine-based or a collagen-based sponge" and then swiping the thus pre-wetted with "a swab comprising gelatine or collagen." Of course, Hahn does not teach or remotely suggest these steps, inasmuch as there is no mention of gelatine-based or a collagen-based sponges in Hahn and there is nothing in the mere mention of "protein-based materials such as collagen and gelatin" as vehicles that would have motivated one skilled in the art to employ a collagen or gelatine sponge to pre-wet a surface prior to using a "a swab comprising gelatine or collagen" to recover a target from a pre-wetted area. Blakesley, on the other hand, discloses a method for "extracting and isolating protein and peptide molecules" from cells comprising "contacting one or more cells or cellular sources with at least one pore-containing matrix" and lysing the cells prior to a collection step wherein the protein and peptide molecules are obtained. see ¶ [0009]. Blakesley teaches that the matrix may be in the form of a "swab tip" and may include "a polyester matrix, a polyolefin matrix, a scintered polyethylene matrix, a nitrocellulose matrix, a cellulose acetate matrix, a cellulose matrix, a porous ceramic matrix, a silica matrix, a polysaccharide matrix (SEPHAROSE, agarose, SEPHADEX, etc.), a polymer matrix (SEPHACRYL, TRISACRYL, TOYOPEARL, BIO-GEL, etc.) and the like -- with no mention of gelatine or collagen. see ¶ [0030]. Yet the Examiner contends that "both the gel material of Blakesley and Hahn are naturally occurring protein-based materials capable of and intended for a substantially identical purpose (collecting skin cells from a target area)" and thus "it would be obvious to one of ordinary skill in the art to modify the article of Blakesley such that the swab is

comprised of collagen-based sponge as taught by Hahn.” This rationale is clearly deficient. Contrary to the Examiner’s misrepresentation of Hahn, there is **no disclosure of a swab comprising collagen**, let alone a collagen-based sponge. Moreover, Hahn discloses collagen and gelatin only as vehicles. It defies any reasonable reading of Hahn to suggest that (i) a “sponge” of these materials is taught or suggested; (ii) a “swab” comprising these materials is taught or suggested; or (iii) that the vehicles of Hahn are for “collecting skin cells from a target area.” The Examiner’s contention that “both the gel material of Blakesley and Hahn are naturally occurring protein-based materials capable of and intended for a substantially identical purpose (collecting skin cells from a target area)” is not well-taken because the protein materials of Hahn are part of a vehicle -- something to be applied to and left on the skin -- whereas the polysaccharide (agarose) of Blakesley is a porous matrix material for collecting and lysing cells. It defies any reasonable reading to suggest that these are used for the “identical purpose.” Moreover, a careful reading of Blakesley reveals that the disclosed method does not recover the target from a pre-wetted area because the target (cells) are lysed in the matrix and thus it is the protein and peptide components within the cell that are recovered rather than the target. For at least the foregoing reasons, Applicants respectfully request withdrawal of the rejection of claim 95.

Having distinguished the independent claims, the dependent claims are believed to be patentable for at least the same reasons. However, Applicants reserve the right to separately address the patentability of those claim in the future, should that become necessary.

The rejection of claims 90, 110 and 112-115 over Hahn in combination with Rosenthal is moot in view of the cancellation of those claims. However, Applicants nevertheless traverse this rejection. Rosenthal relates to “a bioabsorbable heteromorphic sponge comprising a matrix structure of sponge and at least one substructure, wherein the matrix and the substructure are formed of bioabsorbable materials and the sponge comprises at least one pharmacologically active agent” and wherein both the matrix and substructure may be collagen-based. There is no disclosure in Rosenthal of a “swab comprising gelatine or collagen” and thus nothing in the disclosure of Rosenthal rectifies the deficiencies of Hahn. Moreover, since Rosenthal is directed to a sponge which is “bioabsorbable in that it is capable of full degradation and resorption within a patient’s body,” it is irrelevant to, and teaches away from, the instant claims directed to swabs,

devices, kits, and methods for collecting or sampling.

Additional Comments

The Examiner makes certain allegations of fact without providing documentary evidence to support such facts. To the extent that the Examiner is taking Office Notice of such facts, Applicants hereby traverse such finding and kindly request that the Examiner provide documentary evidence establishing the alleged facts so noticed pursuant to §2144.03. Specifically, Applicants request that the Examiner provide documentary evidence that “collagen is protein-based and thus is of natural origin” (p. 4), that ethanol is “an organic buffer” (p. 4), that “microfibrillar collagen is a form of collagen that is also suitable for any application that a collagen is suitable for” (p. 6), and that a blood cell “contains all of the items set forth in claim 120 i.e. leukocytes, erythrocytes, and thrombocytes” (p. 16). The basis of these traversals is that each of the forgoing is scientifically incorrect or incomplete as stated.

Applicants submitted a copy British patent No. GB697,603 with the Information Disclosure Statement filed February 15, 2008. GB 697,603 had been cited in the International Search Report (ISR) and International Preliminary Examination Report (IPER) in connection with the corresponding international PCT application. GB 697,603 is directed to “a forceps device for use with a sponge device for obtaining tumor tissue for microscopic examination.” [GB 697,603, page 1, lines 10-13]. The patent states that “[v]arious kinds of sponge devices may be used as exemplified by cotton gauze, synthetic rubber sponge, natural sea sponge, blotting and tissue paper sponge, gelatin sponge and cellulose sponges of various pore sizes.” [GB 697,603, page 2, lines 8-13]. However, there is no teaching or suggestion in GB 697,603 of using the device to collect a target and to transfer the target from the device to a recovery medium. Rather, it is taught that “small sized pieces or tumor tissue are entrapped or absorbed in the fine interstices, pores or cavities of the sponge device” by rubbing it against a tumor, and these tissue samples are then fixed by immersing the sponge in a bottle of formaldehyde. [GB 697,603, page 1, lines 48-64]. The fixed sample is not subsequently transferred from the sponge but instead is “immersed in heated molten paraffin wax” and cooled to form a solidified “cake embodying the sponge” which may be “sliced to produce tissue thin enough for microscopic examination by transmitted light.” [GB 697,603, page 1, lines 69-84]. Claim 93 is amended herein to require the

additional step of “transferring the target from the swab to a first transfer medium by releasing said target from said swab into the first transfer medium” and newly added independent claim 144 contains the same limitation. Applicants submit that the step of “transferring” fully distinguishes the instant claims from GB 697,603, for at least the reason that that patent does not teach or suggest transferring a target from the sponge to a recovery medium.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.


AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 50-3732, Order No. 13323.105003. Furthermore, in the event that an extension of time is required, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to the above-noted Deposit Account No. 50-3732 and Order No. 13323.105003.

Respectfully submitted,

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